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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,926

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Gregory L. Sundberg

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EXAMINER

EVANISKO, GEORGE ROBERT

ART UNIT

PAPER NUMBER

3762

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/673,926	<b>Applicant(s)</b> SUNDBERG, GREGORY L.	
	<b>Examiner</b> George R. Evanisko	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-11 and 13-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-11, 13-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/14/08 has been entered.

### ***Claim Objections***

Claims 8-11, 13, and 14 are objected to because of the following informalities listed below. Appropriate correction is required.

In claim 8, the last paragraph, “forming helical drive grooves...helix a drive mechanism that...” seems to be worded incorrectly.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Peers-Travarton (4667686). Peers-Travarton shows housing, 12, piston, 40, helix coupled to piston (e.g. figure 2, 30), with a housing portion including a helical segmented guide, 32, that rides

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along the drive mechanism/helical drive grooves (e.g. figure 2, col. 4, lines 10-15), and includes a sleeve of radiopaque material coupled to the housing through the lead.

Claims 15-16, 19, 23, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Vachon (5531780). See, for example, figures 4-9 and corresponding description.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-11, 13, 20-22 and 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travarton in view of Bisping (4282885) or Fahlstrom et al (4913147).

And claims 1-6, 8, 11, 13, 14, 17, 18, 20-22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vachon in view of Bisping (4282885) or Fahlstrom et al (4913147). Peers-Travarton or Vachon discloses the claimed invention except for disclosing part of the fixation helix in a helical recess of a piston, separated by non-recessed portions. Bisping or Fahlstrom teaches that it is known to put nearly the entire part of the fixation helix wire in a helical recess of a piston, separated by non-recessed portions to provide stability to the helix during implantation and extraction (note, the claim is an open ended comprising claim and 1/3 to 1/2 of the wire is in the recess when the entire helix wire is in the recess). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the medical lead as taught by Peers-Travarton or Vachon, the use of the fixation helix in a helical recess of a piston, separated by non-recessed portions as taught by Bisping or Fahlstrom since

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such a modification would provide an implantable lead with part of the fixation helix in a helical recess of a piston, separated by non-recessed portions to provide the predictable results of stability to the helix during implantation and/or extraction. In addition, for claim 12, the claim is a product by process limitation and does not add any further structural limitations to the final product of the helix coupled to the piston. In the alternative, it is well known when connecting two elements to make one diameter smaller than the other diameter to provide the predictable results of a more secure and tight fit of the two elements.

In the alternative for claims 6 and 21, Peers-Travaton or Vachon in view of Bisping or Fahlstrom discloses the claimed invention but does not disclose expressly  $1/3$  to  $1/2$  of the a diameter of the helix within the piston. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the lead as taught by Peers-Travaton or Vachon in view of Bisping or Fahlstrom with  $1/3$  to  $1/2$  of the a diameter of the helix within the piston, because Applicant has not disclosed that  $1/3$  to  $1/2$  of the a diameter of the helix within the piston provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the wire completely in the recess as taught by Peers-Travaton or Vachon in view of Bisping or Fahlstrom, because it securely holds the wire during implantation.

Therefore, it would have been an obvious matter of design choice to modify Peers-Travaton or Vachon in view of Bisping or Fahlstrom to obtain the invention as specified in the claim(s).

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Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Peers-Travatton discussed above for claim 14 or over Peers-Travatton for claims 15 and 16. The modified Peers-Travatton or Peers-Travatton discloses the claimed invention except for the conductor electrically connected to the piston, piston electrically connected to the helix, and active helix. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable heart lead as taught by the modified Peers-Travatton or Peers-Travatton, with the conductor electrically connected to the piston, piston electrically connected to the helix, and active helix since it was known in the art that medical leads use a conductor electrically connected to the piston, piston electrically connected to the helix, and active helix to provide the predictable results of a helical fixation lead that actively directly stimulates cardiac tissue at the fixation site and allows for bipolar pacing and sensing.

Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Peers-Travatton in view of Bisping (4282885) or Fahlstrom et al. Peers-Travatton discloses the claimed invention except for disclosing part of the fixation helix in a helical recess of a piston, separated by non-recessed portions. Bisping or Fahlstrom teaches that it is known to put nearly the entire part of the fixation helix wire in a helical recess of a piston, separated by non-recessed portions to provide stability to the helix during implantation and extraction (note, the claim is an open ended comprising claim and 1/3 to 1/2 of the wire is in the recess when the entire helix wire is in the recess). It would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the medical lead as taught by Peers-Travatton, the use of the fixation helix in a helical recess of a piston, separated by non-recessed portions as taught by

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Bisping or Fahlstrom since such a modification would provide an implantable lead with part of the fixation helix in a helical recess of a piston, separated by non-recessed portions to provide the predictable results of stability to the helix during implantation and extraction.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the modified Vachon as discussed above. The modified Vachon discloses the claimed invention except for the guide being a segmented helical guide. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable lead as taught by the modified Vachon, with the guide being a helical segmented guide since it was known in the art that implantable leads use a guide being a helical segmented guide to provide the predictable result of easily and smoothly advancing the helix from the lead.

### ***Response to Arguments***

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Fischer, Sr. is another example of a helical segmented guide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/  
Primary Examiner, Art Unit 3762

GRE  
11/24/08